MAY - 4 2004

K033216

EXHIBIT 2

Summary of Safety and Effectiveness

The Buzz Group, LLC
420 Lexington Avenue, Suite 2816
New York, NY 10170
Tel: (212) 375-2962
Fax: (212) 375-2918
Contact: David Ortiz, President

1. **Identification of the device**
   Proprietary-Trade Name: Model BZ-576 Automatic Blood Pressure Monitor
   Classification Names: DXN, SYSTEM, MEASUREMENT, BLOOD-PRESSURE, NON-INVASIVE,
   Common/Usual Name: Wrist blood pressure monitor/Body fat meter

2. **Equivalent legally marketed devices**
   This product is similar in function and design to the Omron HEM-757 Automatic Blood Pressure Monitor, K001670

3. **Indications for Use (intended use)**
   Measuring systolic and diastolic blood pressures and pulse rates in adult patients with arm circumference between 5 and 15 inches.

4. **Description of the Device**
   The Model BZ-576 Digital Blood Pressure Monitor uses the oscillometric method with Fuzzy arithmetic for measuring blood pressure, and the high accuracy and repeatability are achieved. The device is ideal for people who frequently monitor their own blood pressure, for its easy way to use at home, at work and during travel. The main components include a cuff, an integrated silicon pressure sensor, an electronic pump, an electronic valve, two buttons, a microcontroller and LCD display. The integrated silicon pressure sensor is used for detecting pressure within the cuff and the pulse wave component during the course of cuff pressure deflation, and guarantees the long period stability. The air pressure of inflation, deflation and rapid release are fully automatic by using an electronic pump and an electronic valve, and a constant deflation speed is controlled in the process of measurement for increasing the accuracy and reducing the measurement time. The blood pressure and pulse values are calculated, and are displayed with "mmHg" or "kPa" on LCD alternatively.

5. **Safety and Effectiveness, comparison to predicate device**
   The results of bench and user/clinical testing indicate that the new device is as safe and effective as the predicate devices.

6. Comparison matrix – new vs. Predicate device

Designation	Omron HEM-757 Automatic Blood Pressure Monitor, K001670	Buzz Group BZ-576
Operating Principle	Oscillometric automated blood pressure monitoring	SAME
Display	LCD: Systolic, Diastolic, Pulse, Low Batt.	LCD: Systolic, Diastolic, Pulse, Low Batt. (SAME) PLUS date and time.
Controls	ON/OFF START M (Memory)	POWER START MEM A MEM B
Power supply	4-AA batteries; AC Adaptor	SAME except no AC Adaptor available
External dimensions	Approx. 4.5" L x 7" W x 2.8" H	Approx 3.8" L x 5.2" W x 1.5" H.
Memory	14 measurements	SAME
Weight	19 oz, 530 g. not including batteries	10.2 oz with batteries (unit) 4.4 oz: cuff
Accessories	Arm cuff, carrying case, instruction manual	SAME

7. Conclusion

After analyzing both bench and clinical testing data, it is the conclusion of The Buzz Group that that the "BZ-576" Automated Blood Pressure Monitor is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2004

The Buzz Group, LLC
c/o Mr. Daniel Kamm
Kamm & Associates
PO Box 7007
Deerfield IL 60015

Re: K033216
Trade/Device Name: "BZ-576" Non-invasive Automatic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: September 30, 2003
Received: October 03, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K033216

Device Name: "BZ-576" Non-Invasive Automatic Blood Pressure Monitor

Indications For Use:

Measuring systolic and diastolic blood pressures and pulse rates in adult patients with arm circumference between 5 and 15 inches.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033216